COMMENTARY: APPLYING THE RULE OF REASON IN THE POST-*ACTAVIS* WORLD

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In FTC v. Actavis, *133 S. Ct. 2223 (2013), the Supreme Court held that in cases challenging alleged "reverse payment" settlements of patent litigation arising in the context of the Hatch-Waxman Act, the Rule of Reason applies—no per se rules, no quick look, no shortcuts.* Actavis *arose in the context of a motion to dismiss and explicitly left to the lower courts the task of structuring the Rule of Reason analysis. Following* Actavis, *how the lower courts should apply the Rule of Reason has been the subject of considerable debate. The FTC and private plaintiffs, as well as law professors aligned with their views, have attempted to find in* Actavis *justifications for injecting shortcuts and presumptions that would undermine the Court's clear holdings. Those efforts have thus far been largely rejected in post-*Actavis *litigation. As we argue, courts should continue to reject such efforts—which rest on presumptions rather than proof—and preserve the integrity of the Rule of Reason.*

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I. INTRODUCTION

In 1898, as a judge on the Sixth Circuit Court of Appeals, William Howard Taft wrote the landmark antitrust decision *United States v. Addyston Pipe & Steel Co.*[1] There, he recognized a distinction between naked and ancillary restraints that would help set the stage for the modern day Rule of Reason. Taft would go on to become President and Chief Justice of the United States. More than a century later, the Supreme Court in *FTC v. Actavis*[2] held that the Rule of Reason applies in cases challenging alleged "reverse payment" settlements of litigation arising in the context of the Hatch-Waxman Act. How the lower courts should apply the Rule of Reason following *Actavis* is the subject of considerable debate; what is clear is that the *Actavis* Court might have done well to draw lessons from Taft's jurisprudence, and from his sage

[1] United States v. Addyston Pipe & Steel Co., 85 F. 271 (6th Cir. 1898), *aff'd* 175 U.S. 211 (1899).

[2] FTC v. Actavis, 133 S. Ct. 2223 (2013).

advice: "Don't write so that you can be understood; write so that you can't be misunderstood."[3]

In the lead-up to *Actavis*, the Federal Trade Commission (the "FTC") and private plaintiffs seeking to challenge so-called "reverse payment" settlements sought a rule of presumptive, if not *per se*, illegality for such agreements. At the same time, parties to such settlements advocated for a rule that rendered them virtually *per se* lawful as long as the settlement was within the term and substance of the patent—dubbed the "scope of the patent test"—which was adopted by a majority of courts led by the Court of Appeals for the Eleventh Circuit. On the strength of a circuit split created by an outlier Third Circuit decision applying a so-called "quick look" Rule of Reason analysis,[4] the Supreme Court took up the question in *Actavis* and rejected both positions. It held that so-called reverse payment settlement agreements challenged in subsequent antitrust litigation must be analyzed under the full Rule of Reason—no *per se* rules, no quick look, no shortcuts.[5]

Following *Actavis*, the FTC and private plaintiffs, as well as law professors aligned with their views, have attempted to find in *Actavis* justifications for injecting shortcuts and presumptions that would undermine those clear holdings. Those efforts have thus far been largely rejected in post-*Actavis* litigation, most notably in *In re Wellbutrin XL Antitrust Litigation*,[6] which was decided by the Third Circuit—the same court that had before *Actavis* adopted a "quick look" approach. We explain below why courts should

[3] Gerald Lebovits, *Free at Last from Obscurity: Achieving Clarity*, 16 SCRIBES J. LEGAL WRITING 127, 127 (2015) (quoting President and later Chief Justice Taft).

[4] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2013), *vacated sub nom*. Merck & Co. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013).

[5] *See Actavis*, 133 S. Ct. at 2237 ("The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason' . . . . We decline to do so.") (citation omitted).

[6] *In re* Wellbutrin XL Antitrust Litig., 868 F.3d 132, 167 (3rd Cir. 2017).

continue to reject such efforts—which rest on presumptions rather than proof—and preserve the integrity of the Rule of Reason.

II. THE TWIN HOLDINGS OF *ACTAVIS*: ALL THE REST IS COMMENTARY

A. Background on Hatch-Waxman Act Features that Incentivize Patent Litigation Settlements Involving "Reverse Payments"

Patent settlement agreements involving so-called "reverse payments" arise most frequently under the Hatch-Waxman Act.[7] The Act allows generic drug manufacturers to obtain expedited Food and Drug Administration ("FDA") approval to market a previously-approved drug by filing an Abbreviated New Drug Application ("ANDA"). When filing an ANDA, a generic manufacturer must certify that the generic drug has the same active ingredients as, and is biologically equivalent to, a previously-approved brand-name drug.[8] To obtain FDA approval, the generic manufacturer must also certify in one of several ways that the generic drug does not infringe valid and outstanding patents. One such way is through a "Paragraph IV" certification, which states that that the patent is either "invalid or will not be infringed by the manufacture, use, or sale" of the generic drug.[9] The first generic manufacturer to file a Paragraph IV certification is eligible for 180 days of market exclusivity, during which time the FDA cannot approve another generic manufacturer's ANDA.[10] Following a Paragraph IV certification, a brand-name manufacturer has forty-five days to file an infringement action, which stays FDA

[7] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301 *et seq.*).

[8] *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv) (2017).

[9] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[10] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

approval of the ANDA for thirty months to allow the infringement action (the Paragraph IV litigation) to proceed.[11]

Typically, because a generic manufacturer that files a Paragraph IV certification has yet to enter the market, it cannot be liable for patent infringement damages.[12] Thus, unlike traditional patent litigation between patent owners and infringers—in which the infringer runs the risk of removal from the market and incurring damages liability for past infringement—the only economic risks that the first filing generic manufacturer runs in litigating are the cost of litigation and the opportunity cost of the 180 days of exclusive generic sales it cannot make if it loses. In contrast, the brand manufacturer faces the risk that its patent is held invalid or non-infringed, which costs it the market exclusivity that comes with owning a valid patent. As a result, while all settlements involve consideration of some sort flowing in both directions, Paragraph IV litigation settlements for a number of years often included a substantial cash payment by plaintiff (brand-name manufacturer) to the alleged infringer (generic manufacturer) as part of the settlement.[13] Because in

11 *See* 21 U.S.C. § 355(j)(5)(B)(iii).

12 *See* Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED CIR. B.J. 47, 51 (2010) ("Unlike the usual patent case, there are ordinarily no damages claims against the generic because Hatch-Waxman forces the litigation to occur in the period prior to marketing by the generic. As a result, no sales or profits are lost by the patentee to the generic. While patent infringement suits are often settled by compromise of a damages claim, that vehicle is typically not available in Hatch-Waxman cases.").

13 Of course, as many have observed, "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement." Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (2003). For example, "traditional" patent infringement cases involving a wide variety of products have been settled on terms that include forgiveness of some or all of the liability for past infringement damages alongside provisions for withdrawal of the infringing product from the market and acknowledgments of validity, enforceability and infringement, and a transfer of "value" from the patent owner to the infringer to facilitate reaching a settlement agreement that

traditional patent litigation cash ordinarily flows from the alleged infringer to the patent owner, the consideration that flows from the plaintiff to the defendant in such Paragraph IV litigation settlements came to be called a "reverse payment."[14]

In *Actavis*, the Supreme Court resolved a circuit split regarding the level of antitrust scrutiny that lower courts should apply to settlements involving alleged reverse payments. The Eleventh Circuit (and others) had applied the "scope of the patent test," holding that reverse payment settlements are lawful so long as they do not restrain trade beyond the legitimate scope of the patent's exclusionary potential.[15] The Third Circuit, meanwhile, applied the "quick look" test. Under that test, a reverse payment settlement is *prima facie* evidence of an unreasonable restraint of trade, and the defendant has the burden of showing procompetitive justifications for the settlement agreement.[16]

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both terminates the challenge to the patent and, often, results in the generic exiting the market or agreeing to pay future royalties to the patentee.

[14] FTC v. Actavis, 133 S. Ct. 2223, 2227 (2013).

[15] FTC v. Watson Pharmaceuticals, 677 F.3d 1298, 1312 (11th Cir. 2012). The Eleventh Circuit's view arguably recognizes—in patent language—the fact that the settlement agreement removes (for the generic manufacturer and the market as a whole) an existing barrier to entry that one cannot be certain would have been lifted in the absence of the settlement. Lifting that veil of uncertainty and assuring that the generic can enter the market (barring other obstacles) is inherently procompetitive. There is no principle in antitrust law that requires parties entering into a procompetitive agreement to negotiate the "most procompetitive" agreement possible. *See, e.g.*, King Drug Co. of Florence v. SmithKline Beecham Corp., 791 F.3d 388, 408–09 (3d Cir. 2015). As such, the Eleventh Circuit's refusal to examine whether, in the absence of a payment the parties might have agreed to a different entry date, or to allow the Federal Trade Commission (the "FTC") or plaintiffs to speculate as to what an optimal entry date would have been, made antitrust sense.

[16] *In Re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), *vacated sub nom*. Merck & Co. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013). The Third Circuit's approach arguably ignores the benefits of the settlement agreement as a whole, and simply assumes either that (i) in the absence of the payment, the parties would have agreed to an earlier entry date *and antitrust law requires them to do so*, or (ii) in the absence of the settlement the generic manufacturer would have prevailed. As noted above,

B. The Holdings

The *Actavis* case must be considered in light of its procedural posture. There, the Eleventh Circuit had affirmed dismissal of a complaint brought by the FTC. The only task before the Supreme Court was to decide whether the FTC's complaint stated a plausible claim.[17]

The Court reversed, holding that the Eleventh Circuit should have permitted the FTC's lawsuit to proceed.[18] The Court held that reverse payment settlements—even where they permit entry within the scope of the relevant patent—can sometimes violate the antitrust laws.[19] But the Court rejected the FTC's position that reverse payment settlement agreements are presumptively unlawful and subject to review under the "quick look" test.[20] Instead, under *Actavis*, courts must scrutinize reverse payment settlement agreements under the "Rule of Reason."[21] The *Actavis* holdings end there. The rest is commentary.

C. The Commentary

Writing for the *Actavis* majority, Justice Breyer did not purport to adopt a new Rule of Reason analysis. Indeed, he explicitly left to the lower courts the task of structuring the Rule of Reason analysis.[22] And, in rejecting the quick-look test, he wrote that "the FTC must prove its case as in other rule-of-reason cases."[23]

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the first assumption is legally untenable. *See supra* note 15. As shown below, the second assumption is inherently speculative, and equally untenable. *See infra* notes 69–73 and accompanying text.

17 *See Actavis*, 133 S. Ct. at 2227.

18 *See id.*

19 *See id.*

20 *See id.* at 2237.

21 *See id.*

22 *Id.* at 2238.

23 *Id.* at 2237.

However, Justice Breyer offered "five sets of considerations" justifying the Court's holding.[24] The "considerations" are, however, laden with conditional language. For instance, he observed that "sometimes" patent settlements will have "genuine adverse effects on competition,"[25] and that "these anticompetitive consequences will at least sometimes prove unjustified."[26] Most notably, he predicted that "it is normally not necessary to litigate patent validity to answer the antitrust question" because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival," and using a "payment . . . to prevent the risk of competition . . . constitutes the relevant anticompetitive harm."[27] Justice Breyer's reliance on words like "sometimes" and "normally suggests" do not, in our view,

[24] *See id.* at 2234.

[25] *See id.* at 2234–35.

[26] *See id.* at 2235–36.

[27] *See id.* at 2236–37. Justice Breyer also observed that "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice," and that parties may still "settle in other ways" such as "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* at 2236–37. Of course, even an entry-date settlement that complies fully with *Actavis* prevents the risk of competition until the agreed-upon entry date. Thus, the prevention of risk alone cannot be the basis for a judgment that a settlement violates the antitrust laws. For this reason, Professor Michael A. Carrier overextends *Actavis* in suggesting that our approach "fails to sufficiently appreciate *Actavis*'s focus on the 'prevent[ion of] the risk of competition' as 'the relevant anticompetitive harm.' *Actavis,* 133 S. Ct. at 2236." *See* Michael A. Carrier, *The Rule of Reason in the Post-*Actavis *World*, 2018 COLUM. BUS. L. REV. 25, 38 n.69 (2018). One might be able to justify using "prevention of the risk of competition" as anticompetitive harm justifying allowing a case to proceed past a motion to dismiss, which is all that Justice Breyer did in *Actavis.* But *Actavis* mandates that alleged reverse-payment settlements be evaluated under the Rule of Reason. *See Actavis*, 133 S. Ct. at 2237. In any event, *Actavis* does not provide a basis for relieving an antitrust plaintiff of the obligation to prove injury in fact—an element of antitrust liability—to obtain relief under the antitrust laws.

provide a basis on which one can impose presumptions and shortcuts on the Rule of Reason analysis required—particularly in light of the holding rejecting the FTC's effort to do just that. More importantly, the majority's casual substitution of presumed patentee "doubts" for actual judicial findings is, as discussed below, particularly troubling and without legal foundation.[28]

Chief Justice Roberts, joined by Justices Scalia and Thomas, dissented. Addressing the tension between patent and antitrust policies at the core of the majority's opinion, he wrote: "The problem, as the Court correctly recognizes, is that we're not quite certain if the patent is actually valid, or if the competitor is infringing it. But that is always the case, and is plainly a question of patent law."[29] Accordingly, Chief Justice Roberts disagreed with Justice Breyer's suggestion that it will not normally be necessary to litigate patent validity to answer the antitrust question:

> [S]ettling a patent claim *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful. This means that in any such antitrust suit, the defendant (patent holder) will want to use the validity of his patent as a defense—in other words, he'll want to say "I can do this because I have a valid patent that lets me do this."[30]

As Chief Justice Roberts recognized, there is tension between the *Actavis* Court's holding mandating that plaintiffs must prove their claims "as in other rule-of-reason cases,"[31] and Justice Breyer's justifications for the Court's holdings.

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28 *See infra* notes 69–73 and accompanying text.

29 *Actavis*, 133 S. Ct. at 2240 (Roberts, C.J., dissenting).

30 *Id.* at 2244.

31 *Actavis*, 133 S. Ct. at 2237.

III. *ACTAVIS* REQUIRES INQUIRY UNDER THE RULE OF REASON—WITHOUT SHORTCUTS

From the dawn of the Rule of Reason in *Addyston Pipe*[32] through modern times, Rule of Reason analysis has grown to embrace a core principle: Judging whether an agreement violates the law requires an analysis of anticompetitive effects.[33] Of course, asking whether an agreement has anticompetitive effects leads to an inevitable question: Compared to what? Answering that question requires benchmarking the resulting market against a market posited, counterfactually, in the absence of the allegedly anticompetitive agreement.[34] That counterfactual market has come to be called the "but-for" world—i.e., what would have happened but for the allegedly anticompetitive agreement.[35] Describing such a but-for world and determining whether the

[32] United States v. Addyston Pipe & Steel Co., 85 F. 271 (6th Cir. 1898), *aff'd* 175 U.S. 211 (1899).

[33] *See* William H. Rooney & Timothy G. Fleming, *Introduction: William Howard Taft, the Origin of the Rule of Reason, and the* Actavis *Challenge*, 2018 COLUM. BUS. L. REV. 1, 14 (2018); *see also* Carrier, *supra* note 27, at 29.

[34] *See, e.g.*, Chicago Bd. of Trade v. United States, 246 U.S. 231, 238 (1918) (explaining that under the Rule of Reason, the court must consider "the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable"); Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 688 (1978) (the Rule of Reason focuses on "challenged restraint's impact on competitive conditions").

[35] That analysis is excused only in per se cases—not because those cases involve a different competitive harm—but because long experience teaches that there is little too potential market benefit to the agreement at issue, and significant if not certain risk of harm, such as agreements among competitors to fix or raise prices, rig bids, or allocate markets. *See, e.g.*, Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma, 468 U.S. 85, 103, 104 (1984); Broad. Music, Inc. v. Columbia Broad. Sys., 441 U.S. 1, 19–20 (1979); Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 692 (1978). In recent decades, the universe of agreements deemed per se unlawful has shrunk, as courts have recognized that agreements previously thought to be always or almost always anticompetitive effect have been shown to yield benefits for competition. *See, e.g.*, Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877 (2007).

post-agreement market is less competitive than the but-for market is an essential step in determining whether the challenged agreement has caused injury to competition. And, of course, injury to competition is a required element of the antitrust violation—no injury to competition, no antitrust violation.[36]

The *Actavis* holdings, which rule out *per se* rules and presumptions, pose a challenge for courts attempting to implement the Rule of Reason in a case involving alleged reverse payments. The starting point for analysis must be a settlement that resolves bona fide patent litigation that either party could conceivably win, as opposed to sham litigation.[37] The settlement typically includes an entry date beyond which a generic challenger might have entered if it won the patent litigation and earlier than it would have entered if it had lost the patent litigation.

The settlement of bona fide patent litigation is both lawful and procompetitive. Among other benefits, settlements provide certainty as to when the patent barrier to entry will be lifted and an entry date earlier than the patent expiration date. That certainty is important to the generic, it is important for the brand, and it is important to the patients and payers. It saves the parties money, business time, and the distraction of litigation. It also relieves the courts and taxpayers of the costs imposed by litigation.

Courts must be disciplined in avoiding unwarranted shortcuts. The marketing phrase "pay-for-delay" carries a presumption that where a patent settlement includes a reverse payment, entry is necessarily delayed beyond what would have transpired in some alternative scenario. But whether a payment that accompanies a patent litigation settlement is a "restraint" at all is a question of fact that must

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[36] *See, e.g.*, PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 337a (4th ed. 2017) ("To say that the plaintiff has not shown any injury to competition is to conclude that the antitrust laws have not been violated at all.").

[37] Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60 (1993).

be proven. To establish that a payment is a restraint requires the plaintiff to show that, without the payment, the market would have been more competitive—i.e., that generic entry would have taken place sooner.

IV. PRESUMPTIONS AND SHORTCUTS THAT THE FTC, PLAINTIFFS, AND PROFESSORS SEEK ARE CONTRARY TO *ACTAVIS*' HOLDINGS AND COULD DAMAGE RULE OF REASON ANALYSIS GENERALLY

Following *Actavis*, however, commentators and plaintiffs have seized on Justice Breyer's commentary in construing the *Actavis* holding to permit shortcuts that replace the traditional analysis of anticompetitive effects under the Rule of Reason in cases involving alleged reverse payments. The approach that Professor Michael Carrier has proposed is one example.[38]

The burden-shifting framework for applying the Rule of Reason that Professor Carrier outlines accurately describes a way to order the process of a Rule of Reason litigation.[39] Under this framework, the Rule of Reason analysis has four potential steps. First, the plaintiff has the burden of showing a substantial anticompetitive effect.[40] Second, if the plaintiff meets its burden, the defendant has the burden of showing a procompetitive justification.[41] Third, the plaintiff can, but need not, show that the restraint is not reasonably necessary to achieve the defendant's objective, or that there are less restrictive alternatives.[42] According to Professor Carrier, if the plaintiff cannot show a less restrictive alternative, the plaintiff does not lose the case; it simply means that the plaintiff does not prevail at step three.[43] Fourth, the court

38 Carrier, *supra* note 27, at 40–43.

39 *Id.* at 29–31.

40 *Id.* at 29.

41 *Id.* at 29–30.

42 *Id.* at 30.

43 *Id.*

must balance the anticompetitive and procompetitive effects.[44] So far so good.

While the process Professor Carrier describes is an uncontroversial description of the litigation process, process does not dictate substance. As noted above, the framework requires a plaintiff to establish, as a predicate for moving forward, a substantial anticompetitive effect.[45] Professor Carrier proposes to allow plaintiffs to satisfy that obligation in reverse payment cases by relying on layers of presumptions that would undermine the Rule of Reason inquiry. In particular, Professor Carrier maintains that the *Actavis* court "adopted shortcuts favoring plaintiffs."[46] He reads into the Rule of Reason analysis Justice Breyer's observation that the size of the unexplained payment may serve as a "workable surrogate" for the strength of the patent.[47] He thus proposes that a plaintiff may meet its burden of showing substantial anticompetitive effects by showing a "limit on generic entry and compensation to the generic." Put another way—the plaintiff merely has to show that a large unexplained payment was made, and the required "anticompetitive effect" of anything other than immediate entry is presumed. According to Professor Carrier, this presents plaintiffs with "powerful tools" for overcoming the first step of the burden-shifting inquiry.[48] Of course, relieving the plaintiff of its obligation to

44 *Id.* Professor Carrier is correct that the application of the Rule of Reason framework is the same whether the plaintiff is the FTC or a private party seeking damages. *See id.* at 44. Both have to establish anticompetitive effects to get past step one of the analysis. As Professor Carrier notes, a private party seeking damages must also prove antitrust injury—i.e., that it suffered injury of the type the antitrust laws were intended to prevent—as a result of the reduction in competition, and to what degree. *See id.* at 42 n.94.

45 *Id.* at 29.

46 *Id.* at 37.

47 *Id.* at 36.

48 While Professor Carrier acknowledges that the burden-shifting framework makes sense as a means for minimizing the number of cases in which courts must balance anticompetitive and procompetitive effects, he proposes an application of the framework that would effectively eliminate

prove anticompetitive effects as it would be required to in any other Rule of Reason analysis gives it a "powerful tool," as it assumes away the core obligation one acquires upon filing an antitrust complaint. Doing so based on the proffered assumptions would be misguided for at least two reasons.

First, it requires reading *Actavis*—a decision on a motion to dismiss—as intending to *sub silentio* upend a century of Rule of Reason jurisprudence by injecting shortcuts and presumptions, despite the Court's affirmative holding explicitly rejecting the FTC's request that it do so. Second, the articulated presumption—that the payment itself can satisfy the step one requirement that the plaintiff show anticompetitive effects in order to shift the burden to the defendant—rests on other, unsustainable presumptions. Once these are examined, the house of cards falls.

Professor Carrier does not explicitly define what constitutes a "large" payment.[49] Nor did the *Actavis* Court. Justice Breyer suggested that a reverse payment reflects "traditional settlement considerations" where it does not exceed "avoided litigation costs."[50] But this observation is insufficient to support the proposition that a payment in excess of avoided litigation costs satisfies the plaintiff's burden to prove anticompetitive effects. The existence of a payment in excess of litigation costs alone does not establish that generic entry would have taken place earlier in the but-

its first step. Indeed, as described above, a "limit on generic entry and compensation to the generic" are features of nearly *every* settlement of litigation that arises under Paragraph IV of the Hatch-Waxman Act. *Id.* at 41. Professor Carrier also states that the *Actavis* Court "was not willing to accept" procompetitive justifications beyond avoided litigation costs and or costs of generic services. *Id.* at 38. Note, however, that the Court expressly stated that "there may be other justifications," and, more fundamentally, that the *Actavis* Court did not purport to *apply* a Rule of Reason analysis; it held only that the FTC had stated a plausible claim such that dismissal was unwarranted. *Actavis*, 133 S. Ct. at 2236.

[49] We agree with Professor Carrier that most courts have held that a payment is not limited to cash.

[50] FTC v. Actavis, 133 S. Ct. 2223, 2236 (2013).

for world.[51] Allowing it to do so would conflict with the express holding in *Actavis* that reverse payment settlement agreements are not subject to review under the "quick look" test, which shifts to defendants in the first instance the burden of proving procompetitive effects.[52]

The eagerness to rely on the payment alone rests on the faulty assumption that it is a reasonable proxy for patent "weakness," which itself relies on two underlying presumptions: First, that the patentee would not pay the money unless it expected to lose the patent case, and second, that the federal judge presiding over the settled Paragraph IV litigation would have seen it the same way. Because each of these assumptions is flawed, the presumptions that Professor Carrier layers on them are equally flawed.

As the Court of Appeals for the Third Circuit in *Wellbutrin XL* recognized, risk aversion makes it difficult to use the size of a reverse payment as a surrogate for patent strength.[53] This is because parties may be willing to accept a settlement payoff that is smaller than the expected payoff in litigation in exchange for certainty. In *Wellbutrin XL*, the court cited a useful example: Consider a lottery ticket that has a fifty percent chance of a $0 payoff and a fifty percent chance of a $100 million payoff.[54] The expected payoff is $50 million, but most people would be willing to accept substantially less (e.g., $20 million) for certainty of a payoff.[55] Accepting $20 million—and thus "paying" $30 million for certainty—does not reflect a belief that a $0 payoff is more than a fifty percent

[51] As an economic matter, there is considerable debate over whether and to what degree a rule prohibiting reverse payments in excess of avoided litigation costs would restrict procompetitive settlements. *See, e.g.*, Aaeron Edlin et al., *Activating* Actavis, 28 ANTITRUST 16 (2013); Barry C. Harris et al., *Activating* Actavis*: A More Complete Story*, 28 ANTITRUST 83 (2014); Aaron Edlin et al., Actavis *and Error Costs: A Reply to Critics*, 14 ANTITRUST SOURCE 1 (2014).

[52] *See Actavis*, 133 S. Ct. at 2237.

[53] *See In re* Wellbutrin XL Antitrust Litig., 868 F.3d 132, 168–69 (3d Cir. 2017).

[54] *See id.* at 168.

[55] *See id.*

risk.[56] The lottery example—which presumes perfect information—thus shows that the size of the "payment" does not serve as a surrogate for the but-for world, even if the parties accurately perceive patent strength.

Professor Carrier describes the "lottery" example as "resuscitat[ing] the risk-aversion defense rejected in *Actavis*."[57] But whether risk aversion is a justification or a defense addresses a point different from the point made in *Wellbutrin* and here. Risk aversion explains why the size of a payment does not necessarily reflect a patentee's view of the strength of the patent.[58] Accordingly, risk aversion is relevant because it negates a presumption that Professor Carrier and others propose be utilized to satisfy *plaintiff's burden* of proving that generic entry would have taken place earlier but-for the parties' settlement. Nor, for that matter, does a patentee's confidence, of lack of it, in its patent—even if it could be inferred from the payment—support any inference as to what a federal judge might have ruled in the settled Paragraph IV litigation, for reasons explained below.[59]

Treating a "large" payment as a surrogate for anticompetitive effects thus requires layers of unsupportable presumptions that are intended to support two alternative ultimate presumptions at the core of the very first step of Rule of Reason inquiry—the requirement that a plaintiff establish an anticompetitive effect. It presumes that, without the payment, a settlement would still have occurred, *and* that it would have included a term for earlier generic entry. Alternatively, it presumes that the generic challenger would have prevailed in the patent litigation. Neither ultimate presumption is grounded in antitrust law.

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[56] *See id.*

[57] *See* Carrier, *supra* note 27, at 40,

[58] *See Wellbutrin XL*, 868 F.3d at 168–69 (rejecting the argument that size of payment is a "surrogate" for the patent's weakness).

[59] *See infra* notes 71–73 and accompanying text.

V. APPLYING THE RULE OF REASON TO "REVERSE PAYMENT" SETTLEMENT AGREEMENTS

In cases following *Actavis*, plaintiffs seeking to establish anticompetitive effects have offered two principal but-for theories. The first theory is that, absent the reverse payment settlement, the parties would have entered into an "alternative settlement" providing for earlier generic entry. The second theory is that, absent the reverse payment settlement, there would have been no settlement, and the generic firm would have prevailed in the underlying patent litigation. Both theories present challenges.

A. But-For World of "Alternative Settlement"

The "alternative settlement" theory poses both doctrinal and evidentiary challenges, and may not provide a satisfactory basis for evaluating anticompetitive effects in a but-for world. As the Third Circuit explained in *King Drug Co. of Florence v. SmithKline Beecham Corp.*, "*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible."[60] Thus, a comparison between an actual, real-world settlement and a hypothetical, "alternative settlement" in the but-for world does not contain a relevant baseline:

> [B]ecause the relevant baseline is the result that would have occurred in the absence of any agreement, it is not a cognizable harm simply to show that the parties might have elected a different settlement agreement more favorable to competition and consumers.[61]

In the view of courts that follow this line of thought, the relevant baseline is the "level of competition that would have

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[60] King Drug Co. of Florence v. SmithKline Beecham Corp., 791 F.3d 388, 408–09 (3d Cir. 2015); *see also In re* Cipro Cases I & II, 61 Cal. 4th 116, 150 n.10 (2015).

[61] *In re* Cipro Cases I & II, 348 P.3d 845, 864 n.10 (2015).

obtained absent settlement, i.e., if the parties had litigated validity/invalidity and infringement/noninfringement to a judicial determination."[62] This approach recognizes that the payment at issue is part of a larger procompetitive settlement, and properly declines to impose an obligation on the parties to reach the most procompetitive agreement possible.

This brings us back to William Howard Taft and *Addyston Pipe*. If there is a doctrinal basis that might justify the "alternative settlement" theory—or anything remotely like it—it may be the ancillary restraint doctrine first articulated by then-Circuit Judge Taft:

> [N]o conventional restraint of trade can be enforced unless the covenant embodying it is merely ancillary to the main purpose of a lawful contract, and necessary to protect the covenantee in the enjoyment of the legitimate fruits of the contract, or to protect him from the dangers of an unjust use of those fruits by the other party.[63]

Of course, before one can determine whether a restraint is "ancillary," one must identify the restraint. Presumably, plaintiffs in so-called "reverse payment" cases would argue that the restraint is defined by the period before entry, which they assume (but at some point would have to prove) would have been shorter but for the payment. Or, they could argue that the mere presence of the payment itself is the restraint. Either way, whether a term is ancillary, and thus permissible, depends on whether the challenged term was necessary to achieve the lawful objectives of the agreement.[64] In the context of a patent settlement agreement involving alleged reverse payments, the plaintiff's burden would be to show that the alleged payment (and entry date agreement) was not

62 *Id.* at 864.

63 United States v. Addyston Pipe & Steel Co., 85 F. 271, 272 (6th Cir. 1898), *aff'd* 175 U.S. 211 (1899).

64 *See, e.g.*, Broad. Music, Inc. v. Columbia Broad. Sys., 441 U.S. 1, 21–22 (1979); Polk Bros. Inc. v. Forest City Enters., Inc., 776 F.2d 185, 189–90 (7th Cir. 1985); L.A. Mem'l Coliseum Comm'n v. Nat'l Football League, 726 F.2d 1381, 1395 (9th Cir. 1984).

necessary to achieve the settlement, the presumptively lawful purpose of which was to eliminate the uncertainty as to whether and when the existing patent barrier to entry would be lifted, as well as the continuing burden and cost of litigation on the parties, the court, and the taxpayers.[65] If the plaintiff cannot meet this burden, the court should grant summary judgment in favor of the defendants.

Whether a payment was necessary to achieve the lawful objectives of a patent settlement agreement is a question of fact. The Third Circuit in *Wellbutrin XL* explained that, to withstand summary judgment, a plaintiff must produce evidence from which a reasonable jury could conclude that, more likely than not, the parties *would* have reached an alternative settlement in the but-for world.[66] In practice, even where the evidence of settlement discussions is voluminous, there may not be evidence that would permit a plaintiff to meet its burden. The plaintiff cannot meet its burden merely by showing that the parties *may* have been able to reach an alternative settlement.[67] Such a showing would simply be too speculative. And, of course, a plaintiff cannot meet its burden by showing that, absent the payment, the parties would have entered into "alternative settlement," but without an earlier

65 The Court in one post-*Actavis* decision framed the "alternative settlement" scenario in similar terms, noting that there may be injury to competition "if there is evidence in the but-for world that the parties would have reached an agreement to drop the patent litigation in exchange for early generic entry into the market" without a reverse payment. United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA ("*Lidoderm*"), No. 14-MD-02521-WHO, 2017 WL 5068533, at *10 (N.D. Cal. Nov. 3, 2017). Arnold & Porter is counsel for one of the defendants in *Lidoderm*. While this article notes the *Lidoderm* court's holding on summary judgment, as noted above, this article represents the views of its authors, and should not be read as representing the views of any other person or entity, including Arnold & Porter or any of its clients.

66 *See In re* Wellbutrin XL Antitrust Litig., 868 F.3d 132, 167 (3rd Cir. 2017); *see also Lidoderm*, 2017 WL 5068533, at *11 (endorsing "alternative settlement" theory to the extent that it "shows but-for the reverse-payment agreement, the parties *would* have reached a settlement that was still anti-competitive and caused unjustified harm to consumers") (emphasis added).

67 *See Wellbutrin XL,* 868 F.3d at 167.

entry date. Under that scenario, there would have been no anticompetitive effect.

To date, in the limited set of cases following *Actavis*, there is no reported example of a case in which a plaintiff has successfully proven that the defendants would have reached an alternative settlement in the but-for world.[68]

B. But-For World of "No Settlement"

In the "no settlement" scenario, the underlying litigation continues. In this scenario, a plaintiff can show that earlier entry would have taken place in the but-for world only by showing that the alleged generic infringer would have won the underlying patent litigation (by invalidating the patent or showing non-infringement). As noted, the but-for counterfactual essential to the "no settlement" scenario is patent litigation in which either party "could realistically expect success on the merits."[69]

The Supreme Court appears to have been unanimous in the view that litigating the settled patent case is not the correct path,[70] and for good reason. It is important to note that the question in the subsequent antitrust case is not—and should not be—whether the patent is valid or infringed. Rather, it is whether the federal judge presiding over the settled patent case would have, in the absence of the

[68] In *In re* Nexium (Esomeprazole) Antitrust Litigation, the First Circuit held explained that the trial court verdict "reflected the jury's finding that [brand manufacturer] AstraZeneca would not have agreed to settlement terms with a license date earlier than May 27, 2014, the date on which two of its medical patents expired." 842 F.3d 34, 64 (1st Cir. 2016). In *Lidoderm*, the court held that plaintiffs' "alternative settlement" theory was legally cognizable and that there was sufficient evidence to deny summary judgment. *Lidoderm*, 2017 WL 5068533, at *10, *13. The *Lidoderm* case settled in February 2018, shortly before trial.

[69] Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60 (1993).

[70] *Actavis*, 133 S. Ct. at 2236–37; *id.* at 2244 (Roberts, C.J., dissenting).

settlement, ultimately found that the patent was invalid or not infringed.[71]

Attempting to use a "large" payment as a surrogate for who would have prevailed in the underlying litigation is especially problematic. The payment does not show who would have won the litigation; at most it can be read to suggest that the patentee had less confidence in what the judge might do than the absence of a payment would suggest, if one ignores entirely the risk aversion issue described in *Wellbutrin XL* and above.[72] But what the patentee fears is not the issue; the issue is what the judge in the underlying patent litigation would have found. We are aware of no legal foundation for substituting a party's risk-assessment for a judicial outcome.

Moreover, no later antitrust jury should be permitted to try to intuit what that federal judge would have done for two reasons. First, the exercise is inherently speculative, and it inappropriately relies on predictions about potential judicial outcomes.[73] Second, the antitrust jury will have information that would have been unavailable to the judge in the underlying patent litigation, for good reason—that the patent litigation settled, and on what terms. Because such

[71] Hatch-Waxman cases involve no claims for damages because the "act of infringement" is a statutory fiction—the filing or the Paragraph IV certification. *See Actavis*, 133 S. Ct. at 2228 (citing 35 U.S.C. § 271(e)(2)(A)); Senju Pharm. Co. v. Apotex Inc., 746 F.3d 1344, 1350 (Fed. Cir. 2014). They are therefore ordinarily tried to judges. *See, e.g.*, Novartis Pharm. Corp. v. Roxane Labs., Inc., No. 08-CV-3853 DMC, 2009 WL 1140440, at *1 (D.N.J. Apr. 28, 2009); Biovail Labs., Inc. v. Torpharm, Inc., No. 01 C 9008, 2002 WL 1732372, at *2 (N.D. Ill. July 25, 2002). As a result, any approach that involves an antitrust jury later making its own determinations of validity and infringement, rather than confining itself to deciding what the patent litigation judge would have done, risks migrating infringement and validity determinations originally committed to a judge to a later antitrust jury. Patent owners settling Paragraph IV cases would thus have to consider whether they want their patents tested by a judge or a jury in deciding whether to settle the Paragraph IV case, putting a new risk factor into the settlement calculus with unknown consequences.

[72] *See supra* notes 53–58 and accompanying text.

[73] *See* Joshua B. Fishman, *The Circular Logic of* Actavis, 66 AM. U. L. REV. 91, 96 (2016).

information is recognized as prejudicial, had the settlement negotiations failed and the litigation proceeded, such evidence would ordinarily be precluded from trial in the patent litigation under Federal Rule of Evidence 408. Consequently, there is no way to reconstruct the but-for world as it would have existed—i.e., the mind of a federal judge deciding validity and infringement based on the evidentiary record available at the time the Paragraph IV litigation would have been tried.

The proffered alternatives to litigating what would have happened in the underlying patent case are thus entirely unsatisfying. As a result, if the evidence at trial shows that, absent the challenged payment, the settlement would not have happened, the court should grant summary judgment for the defendant(s).

Fortunately, courts have to date largely rejected efforts by plaintiffs to use payment as a proxy for a patent's weakness or as a prediction of what would have happened in any earlier Paragraph IV litigation. But how they have done so has been imperfect at best. Some have required that plaintiffs introduce some evidence on the merits of the underlying patent litigation. For example, in *Wellbutrin XL*,[74] the district court explained that the "existence of a valid and uninfringed patent would interfere with the plaintiffs' chain of causation: a valid patent independently precludes competition apart from any agreement and an 'at-risk' launch is unlawful absent a later finding of patent invalidity or non-infringement." Without evidence to show that patents would have been declared invalid or that an at-risk launch would not have infringed the patents, the "patent served as an independent regulatory bar to a generic's launch."[75]

The Third Circuit affirmed, making clear that "in order to evaluate the merit of the litigation-based scenario, we must

[74] *In re* Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 764 (E.D. Pa. 2015) (internal quotation marks omitted).

[75] *Id.* at 767.

consider the substance of that underlying litigation."[76] In a footnote, the court addressed Justice Breyer's commentary that it normally will not be necessary to litigate patent validity to answer the antitrust question," which Chief Justice Roberts had criticized as implausible. The court observed that the present case appeared to vindicate the Chief Justice's analysis, and that "we cannot resolve this aspect of the case without considering the merits of the underlying patent case."[77]

In *In re Nexium (Esomeprazole) Antitrust Litigation*, the Court of Appeals for the First Circuit likewise rejected plaintiffs' argument that they should not have to prove invalidity or non-infringement to pursue an at-risk launch theory.[78] There, the court explained that plaintiffs failed to provide sufficient evidence that "the brand-name's patents would have been declared invalid or that an 'at risk' launch would not have infringed the patents," and "without such evidence, the patent served as an independent regulatory bar to a generic's launch."[79] Thus the plaintiffs could not establish that the challenged settlement, rather than the legitimate operation of the patents, caused their alleged injuries.[80]

More recently, in *Lidoderm*, the court held that a plaintiff must provide "some evidence" that the generic could have won the patent litigation.[81] The court observed that "some

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76 *In re* Wellbutrin XL Antitrust Litig., 868 F.3d 132, 167 (3d Cir. 2017); *see also* Apotex, Inc. v. Cephalon, Inc., 255 F. Supp. 3d 604, 614 (E.D. Pa. 2017) (explaining that the "clear import of *Nexium* and *Wellbutrin* [*XL*]is that a plaintiff must offer some evidence of non-infringement or patent invalidity in order to proceed on an at-risk launch theory of causation").

77 *In re Wellbutrin XL*, 868 F.3d at 167 n.58.

78 *In re* Nexium (Esomeprazole) Litig., 842 F.3d 34, 62–64 (1st Cir. 2016).

79 *See id.* at 63 (internal quotation marks omitted).

80 *See id.*

81 *Lidoderm*, No. 14-MD-02521-WHO 2017 WL 5068533, at *5 (N.D. Cal. Nov. 3, 2017); *see also* In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. CV 14-MD-02503, 2018 WL 563144, at *14 (D. Mass. Jan. 25, 2018) (same). Like other courts, the courts in *Lidoderm* and

evidence" is "not the same as requiring plaintiffs to prove that the generic defendant *would have* won, only that it *could* have."[82] That observation may have addressed the court's valid concern about litigating the patent case,[83] but it also reveals the flaw in adopting a "some evidence" standard. As noted above, in a "no settlement" scenario, "some evidence" that a generic defendant *could* have won the patent litigation is the *starting point* for analysis—absent proof that the litigation was a sham, either party "could realistically expect success on the merits" of the underlying patent case.[84] Thus, requiring "some evidence" that the generic could have won the patent litigation—i.e., the mere possibility of generic entry—to stand in for proving the existence of a but-for world by a preponderance of the evidence is tantamount to requiring no evidence at all.

These courts were correct in concluding that a reverse payment alone cannot be a proxy for the likely outcome of the underlying patent case. However, their willingness to consider evidence as to validity or infringement invites similar shortcuts and risks imposing later judgments as to the patent's strength on the relevant question—namely, what would the judge have done in the underlying Paragraph IV litigation—thus reflecting a lack of focus on the inherent speculative-ness of attempting to construct a but-for world around an underlying settled litigation. For the reasons provided above, courts should not permit parties, or juries, to speculate as to what a federal judge in a prior litigation would have decided.

Solodyn did not ground their analyses in application of the Rule of Reason, focusing instead on "causation." *Id.*

82 *Id.* at *4 (emphasis in original).

83 *See id.* at *5.

84 Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60 (1993).

VI. CONCLUSION

If the case law since *Actavis* has made anything clear, it is that the decision generated more questions than it answered. The *Actavis* holdings on the motion to dismiss at issue are clear—no *per se* rules, no quick looks, no presumptions. The majority's commentary, while meant to respond to risks identified by the dissent, makes for interesting intra-judicial debate but does not support the subsequent efforts to undermine the Court's clear holdings. To date, the lower courts have largely rejected those efforts. But it is likely only a matter of time before more courts succumb to the temptation to use the shortcuts that *Actavis* rejected. Accordingly, it is unlikely that *Actavis* will be the final opportunity for the Supreme Court to address challenges to patent settlement agreements in the Hatch-Waxman context.